



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 18, 2017

PFM Medical, Inc.
Salvadore F. Palomares, RAC
Director of Regulatory Affairs
2605 Temple Heights Drive, Suite A
Oceanside, CA 92056

Re: K093796
Trade/Device Name: Asept Peritoneal Drainage System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: PNG
Dated: December 10, 2010
Received: December 11, 2010

Dear Salvadore F. Palomares:

This letter corrects our substantially equivalent letter of February 26, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K093796
181

510(k):

K093796

Device Name:

Asept Peritoneal Drainage System

Indications for Use:

The Asept Peritoneal Drainage System is indicated for periodic drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long term access of the peritoneal cavity in order to relieve symptoms such as dyspnea.

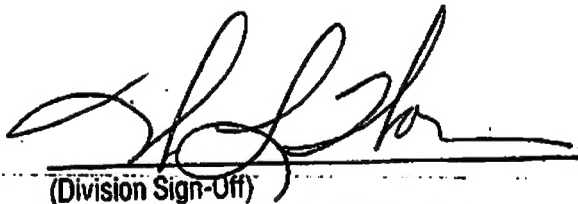
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K093796

K093796
1x1

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: PFM Medical, Inc
Address: 2605 Temple Heights Drive
Suite A
Oceanside, CA 92056
CONTACT PERSON: SALVADORE F. PALOMARES, RAC

FEB 26 2010

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Trade Name: Asept Peritoneal Drainage System
Common Name: Catheter, Peritoneal, Long-Term Indwelling and Accessories
Classification: FJS

Equivalent Devices:

Manufacturer: Denver Biomedical (Cardinal Health)
Name: Pleurx Peritoneal Catheter Kit and Pleurx Drainage Kits
510(k) #: K051711

Manufacturer: PFM Medical
Name: Asept Pleural Drainage System
510(k) #: K093307

Device Description:

The Asept Peritoneal Drainage System is a tunneled, indwelling catheter used to drain accumulated fluid from the abdomen. The catheter is implanted in the patient's peritoneal cavity enabling the patient to perform periodic peritoneal drainage at home or hospital. The primary components of the system are the Asept indwelling Peritoneal Catheter and the Asept Drainage Kit. The proximal end of the indwelling catheter has a valve that prevents fluid or air from moving in or out of the peritoneal space until the valve is breached. The valve can be breached by the Asept Peritoneal Drainage catheter connected to wall suction or pleurovac or vacuum bottles. The Asept Peritoneal Drainage System provides patients with a convenient way to relieve malignant ascites symptoms at home.

Intended Use:

The Asept Peritoneal Drainage System is indicated for periodic drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long term access of the peritoneal cavity in order to relieve symptoms such as dyspnea.

Performance Data:

In vitro testing was performed on the Asept Peritoneal Drainage System to assure reliable design and performance in accordance with BS EN 1618-1997. Testing includes leakage, flow rate, tensile strength, and corrosion.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

Biocompatibility:

Materials used in the Asept Peritoneal Drainage System meet the requirements of ISO 10993 or identical to legally marketed devices.